



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 6, 2020

Dolana Blount
VP of Regulatory Affairs
ETI H2O
1725 Gillespie Way
El Cajon, CA 92020

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Axen® 30
EPA Registration Number: 72977-3
Application Date: March 11, 2020
Decision Number: 560973

Dear Ms. Blount:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, or enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Adenovirus Type 2, Rhinovirus Type 37, and Feline Calicivirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

Axen® 30

[Disinfectant], [Fungicide] [& Virucide*]

[Disinfects and Deodorizes]

- [Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices] • [Trucks] •
- [Trailers] • [Shipping Containers]
- [Rail Cars]

Manufactured by ETI H2O
 A Division of PURE Bioscience
 1725 Gillespie Way
 El Cajon, CA 92020
 EPA REG. No. 72977-3
 EPA EST. No. 72977-CA-001
 Net Vol.

[Batch Number – may appear on container]

Active Ingredient

Silver [†]	0.003%
Citric Acid	4.846%

Other Ingredients

	95.151%
Total	100.000%

[†] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN



NOTE: [Bracketed] text is optional wording ***Bold/italicized text is information only and not part of the label.***

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 [this product] is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30** [this product] should be used on non-porous environmental hard surfaces in ***Choose from the list below***

- | | | | |
|---------------------------|----------------------------|-------------------------|-------------------------|
| Homes [households] | patient transfer vehicles | prisons [jails] | airports |
| offices | hotels | kitchens | school buses |
| hospitals | restaurants | [public] restrooms | cars [autos] |
| nursing homes | bars | bathrooms | RV [mobile home] |
| medical clinics | supermarket[grocery store] | washrooms | trucks |
| dental clinics | schools | laundry rooms | trailers |
| infirmary | colleges | bedrooms | shipping containers |
| blood bank(s) | dorm rooms [dormitories] | basements | rail cars |
| pharmacies | churches | garage(s) | subways |
| laboratories | shelters | workshops | trains |
| funeral homes | military [installations] | attics | airplanes |
| veterinary clinics | [locations] | locker rooms | ships |
| animal shelters | day care facilities | exercise facilities | cruise ships |
| kennels | daycare centers | gyms [gymnasium] | busses |
| cages | nurseries | beauty shops or salons) | other public |
| stables | playrooms | barber shops | transportation vehicles |
| catteries | playgrounds | spas | |
| animal transport vehicles | recreational facilities | health clubs | |
| ambulances | | laundromats | |

AXEN® 30 [this product] has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including ***Choose from the list below***

- | | | | |
|-----------------------------------|----------------------|-------------------------------------|-------------------------------|
| walls | stove tops | jungle gyms | desks |
| floors | bed frames | playhouses | grocery carts |
| counters | wheelchairs | baby furniture | computer keyboards |
| cabinets [cabinet handles] | over-bed tables | child car seats, hard surfaces only | tanning beds |
| sinks | examination tables | booster chairs [seats] | sports equipment |
| tubs | waste containers | strollers [stroller handles] | pharmacy equipment |
| exterior toilet [urinal] surfaces | tables | cribs | FLAVORx® equipment |
| faucet handles | chairs | playpens | Pharmacy dispensing equipment |
| showers | patio furniture | activity centers | cat litter boxes |
| doorknobs | equipment tables | diaper pails | animal cages [carriers] |
| handrails | lab benches | diaper changing tables | |
| light switch covers | [AC] [heating] vents | potty[training] seats | |
| telephones | children's toys | laundry hampers | |
| remote control (s) | toys | bathroom counters | |
| appliances | toy boxes | kitchen counters | |
| | play tables | | |

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

General Information

AXEN® 30 [this product] **successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):**

Organism	Kill Time
# <i>Pseudomonas aeruginosa</i>	30 seconds
# <i>Salmonella enterica</i>	30 seconds
<i>Staphylococcus aureus</i>	2 minutes
<i>Listeria monocytogenes</i>	2 minutes
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	2 minutes
<i>Escherichia coli</i> O157:H7	2 minutes
<i>Acinetobacter baumannii</i>	2 minutes
<i>Campylobacter jejuni</i>	2 minutes
Trichophyton mentagrophytes (Athlete’s Foot Fungus)	10 minutes
*HIV type 1- [Strain HTLV IIIB]	30 seconds
*Herpes Simplex Type 1 [VR-733 F(1) Strain]	1 minute [60 seconds]
*Rotavirus	3 minutes
*Human Coronavirus	3 minutes
*Influenza A (H1N1)	1 minute [60 seconds]
*Swine Influenza A (H1N1)	1 minute [60 seconds]
*Respiratory Syncytial Virus [RSV]	3 minutes
*Adenovirus Type 2	3 minutes
*Equine Herpes Virus Type 1	3 minutes
*Murine Norovirus	10 minutes
* Norovirus [as Feline Calicivirus]	10 minutes
*Avian Influenza A	10 minutes
*Influenza A [VR-544, Hong Kong strain]	10 minutes
*Rhinovirus [R37 VR-1147, Strain 151-1]	10 minutes
*Polio Type 2, [VR-1002, Lansing Strain]	10 minutes

[Fungicidal Activity: AXEN® 30 [this product] is effective against *Trichophyton mentagrophytes*, the Athlete’s foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.]

[Deodorizes: AXEN® 30 [this product] reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.]

APPLICATION INSTRUCTIONS

Pre-clean surfaces prior to using this product.

General Disinfection:

For general disinfection and control of the bacteria *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, *Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA-PVL), *Escherichia coli* O157:H7, *Acinetobacter baumannii* and *Campylobacter jejuni* the surface must be completely wet with **AXEN® 30** [this product] for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™** [this product] provides residual protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* up to 24 hours after initial application. Do not [touch] [contact] treated surface after application if residual protection is to be maintained..

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill bacteria, [apply] [spray] [mist] SDC 3A [this product] to the surface until thoroughly wet for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30** [this product] provides residual protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* up to 24 hours after initial application. Do not [touch] [contact] treated surface after application if residual protection is to be maintained.

Fungus Control:

For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30** [this product] for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill fungus, [apply] [spray] [mist] **AXEN® 30** [this product] to the surface until thoroughly wet for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

***Viral Control:**

To kill Herpes Simplex Type 1 [F(1) Strain], Rotavirus, Human Coronavirus, Norovirus [as Feline Calicivirus], Murine Norovirus [MNV-1], Influenza A (H1N1), Swine Influenza A (H1N1), Avian Influenza A, Influenza A Virus [Hong Kong strain], Rhinovirus [R37 Strain 151-1], Respiratory Syncytial Virus [RSV], Adenovirus Type 2, Equine Herpes Virus Type 1 and Polio Virus Type 2 [Lansing Strain] the surface must be completely wet with **AXEN® 30** [this product] for 10 minutes. The surface may then be wiped dry with a clean towel.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill viruses, [apply] [spray] [mist] **AXEN® 30** [this product] to the surface until thoroughly wet for 10 minutes. The surface may then be wiped dry with a clean towel.

Note to Reviewer: The following are optional phrases as outlined in the EPA's Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)

[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. **AXEN® 30** [This product] is a broad-spectrum hard surface disinfectant that has been shown to be effective against [Influenza A Virus (H1N1)], [Influenza A Virus (H3N2)], [Avian Influenza A Virus] and [Swine Influenza A Virus (H1N1)] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).]

AXEN® 30 [[This product] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.]

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks and eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30** [this product] to area to be treated. The surface must be completely wet with **AXEN® 30** [this product] for 30 seconds. The surface may then be wiped dry with a clean towel. This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Optional refill instructions

To refill [spray bottles]:

1. [REMOVE] Remove trigger sprayer [or cap] from empty bottle
2. [POUR] Remove cap from refill and pour contents directly into empty [bottle].
3. [USE] Replace trigger sprayer and use as you normally would.

This statement will be used on NONREFILLABLE CONTAINERS.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing.

Pesticide Disposal: Nonrefillable Container. Do not reuse or refill this container –or- [Refill only with this product. Do not reuse or refill except as described in the directions for use.]. If empty: Place in trash or offer for recycling if available. Rinse thoroughly before discarding in trash or recycling.

This statement will be used on REFILLABLE CONTAINERS (typically 55 gallons or larger).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in original container

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a national Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Container Handling: Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents from this container into a mix tank or storage tank. Fill the container about 1/4 full with solvent used in the end use product. Replace and tighten closures. Agitate vigorously or recirculate water with a pump for 2 minutes. Pour or pump rinsate into mix tank or rinsate collection system for later use or disposal. Repeat this rinsing procedure two more times

IN CASE OF EMERGENCY

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 (*or other emergency service provider*) for emergency medical treatment information.

Optional Marketing Phrases

[Kills] [Eliminates] [Effective against] *Choose one or more from the list below:*

- Salmonella enterica* [in 30 seconds[†]]
- Pseudomonas aeruginosa* [in 30 seconds[†]]
- Staphylococcus aureus*
- Listeria monocytogenes*
- Acinetobacter baumannii* [in 2 minutes]
- Campylobacter jejuni* [in 2 minutes]
- MRSA or [Methicillin Resistant Staph] or [Methicillin Resistant *Staphylococcus aureus*]
- CA-MRSA or [Community Associated MRSA] or [Community Associated Methicillin Resistant *Staphylococcus aureus*]
- CA-MRSA-PVL
- VRE or [Vancomycin-resistant Enterococcus] or [Vancomycin resistant Enterococcus faecium]
- Escherichia coli O157:H7
- Tricophyton mentagrophytes
- HIV [in 30 seconds[†]]
- Herpes Simplex Virus
- Influenza A Virus
- Rhinovirus
- Polio Virus Type 1
- Rotavirus
- Human Coronavirus
- Norovirus virus [as Feline Calicivirus]
- Avian Influenza A on pre-cleaned environmental hard surfaces
- Respiratory Syncytial Virus [RSV]
- Adenovirus [type 2]
- Influenza A (H1N1) [in 1 minute]
- Swine Influenza A (H1N1) [on pre-cleaned environmental hard surfaces] [in 1 minute]
- Equine Herpes virus type 1
- Murine Norovirus [in the presence of 5% soil]

- Kills germs in 30 seconds[†]
- Kills common household germs
- Kills germs [on surfaces you touch most]
- Kills common household germs including [*Salmonella enterica*], [*Staphylococcus aureus*], [*Listeria monocytogenes*], and [*E. coli*].
- Kills [*Salmonella*], [*Staphylococcus*], [*Listeria*], and [*E. coli*].
- Kills – [Bacteria], [Fungus] and [Virus*]
- Disinfects common household surfaces
- Kills [common] cold] and [flu] virus[s]
- Can help reduce the risk [danger] of cross contamination
- Disinfectant, Fungicidal & Virucidal Spray
- [Patented] Silver [Ion] Formula
- No dulling residue
- Disinfects without bleaching
- No harsh chemical smell
- Odorless
- Disinfects household surfaces
- No Mixing Required
- Powered by [Axenohl®] [SDC 2400] [Axenohl Alternate brand name]
- For daily use
- Refill
- [Worldwide] Patented formula
- [U.S.Patent(s) 6,197,814 ; 6,583,176, [additional patent numbers as issued]
- Other patents pending
- Use for a [fresh] [home] [environment] [kitchen]
- Commercial [Line] [Disinfectant]

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

Industrial [Line] [Disinfectant]
Hospital [Line] [Disinfectant]
Healthcare [Line] [Disinfectant]
Consumer [Line] [Disinfectant]
Retail [Line] [Disinfectant]
Freight [Line] [Disinfectant]
Janitorial [Line] [Disinfectant]

Optional marketing phrases continued

Janitorial Disinfectant
Odoban® [Commercial], [Janitorial], [Earth Choice] (use restricted to the trademark owner)
[FAST], [EASY], [EFFECTIVE]
[Antimicrobial] [antibacterial] disinfectant
Leaves surfaces disinfected
For use on high touch surfaces
Travel size
For use in *(insert use site from label)*
For use on *(insert use surface from label)*
[Ideal for] [Formulated for] [Hospitality Environment(s)] [Institutional] [Childcare Environment(s)] [Medical Environment(s)] [Nursing Environment(s)] [Healthcare Environment(s)] [Athletic Environment(s)] [Educational Environment(s)]
A New Generation of Protection
A New Generation Disinfectant
As seen on TV *may include graphic*

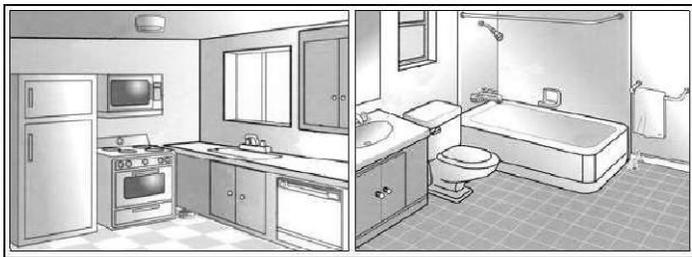


Made in the USA [may include graphic of American flag]
This product has demonstrated effectiveness against Influenza A Virus [Avian Influenza A Virus] [Swine Influenza A Virus] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
Kills Pandemic 2009 H1N1 influenza A virus.
Use to disinfect FLAVORx® equipment
Recommended for use on FLAVORx® equipment

KEY:

***-Refer to viruses ‡-Refer to organisms controlled with 30 second kill time**

Optional graphics for back of label (graphics are larger here than they will appear on the label)



only and not

THE FOLLOWING TABLE IS OPTIONAL TEXT:

[

Organism	ID
<i>Pseudomonas aeruginosa</i>	ATCC#15442
<i>Staphylococcus aureus</i>	ATCC#6538
<i>Salmonella enterica</i>	ATCC#10708
<i>Listeria monocytogenes</i>	ATCC#19111
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	ATCC#700221
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	ATCC#700698
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	NRS123, USA 400
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	NRS 192
<i>Escherichia coli</i> O157:H7	ATCC#43888
<i>Acinetobacter baumannii</i>	ATCC#19606
<i>Campylobacter jejuni</i>	ATCC#29428
Trichophyton mentagrophytes (Athlete's Foot Fungus)	ATCC#9533
*HIV type 1- Strain HTLV IIIB	HTLV-IIIB
*Herpes Simplex Type 1 VR-733 F(1) Strain	ATCC VR-733
*Rotavirus	Strain WA, Ottawa
*Human Coronavirus	ATCC VR-740
*Influenza A (H1N1)	ATCC VR-1469
*Swine Influenza A (H1N1)	ATCC VR-333
*Respiratory Syncytial Virus [RSV]	ATCC VR-26
*Adenovirus Type 2	ATCC VR-846
*Murine Norovirus	MNV-1.CW1
* Norovirus [as Feline Calicivirus]	ATCC VR-782
*Avian Influenza A	ATCC VR-2072
*Influenza A [VR-544, Hong Kong strain]	ATCC VR-544
*Rhinovirus [R37 VR-1147, Strain 151-1]	ATCC VR-1147
*Polio Type 2, [VR-1002, Lansing Strain]	ATCC VR-1002

]

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

Emerging Viral Pathogen Claims

[Product name] [this product] qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below..

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Nonenveloped viruses
- Small, Nonenveloped viruses

For an emerging viral pathogen that is a/an	...follow the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus Type 2
Large, non-enveloped virus	Rhinovirus Type 37
Small, non-enveloped virus	Rhinovirus Type 37 Feline Calicivirus (surrogate for Norovirus)

[Product name] [this product] has demonstrated effectiveness against viruses similar to [***name of emerging virus***] on hard, nonporous surfaces. Therefore, [product name] [this product] can be used against [***name of emerging virus***] when used in accordance with the directions for use against [***name of supporting virus(es)***] on hard, nonporous surfaces. Refer to the [CDC -or- OIE] website at [***pathogen-specific website address***] for additional information.

-or-

[***Insert name of illness/outbreak***] is caused by [***insert name of emerging virus***]. [Product name] [this product] kills similar viruses and therefore can be used against [***name of emerging virus***] when used in accordance with the directions for use against [***name of supporting virus(es)***] on hard, nonporous surfaces. Refer to the [CDC -or- OIE] website at [***pathogen-specific website address***] for additional information.

{Note to Reviewer: These statements for claims against emerging viral pathogens shall not appear on marketed (final print) product labels.}